

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Harold BROWN
Serial No.: 08/241,692 Group: 1211
Filed: May 12, 1994 Examiner: H. Lee
For: A PHARMACEUTICAL COMPOSITION OF COMPLEX
CARBOHYDRATES AND ESSENTIAL OILS AND METHODS OF
USING THE SAME

DECLARATION UNDER 37 CFR 1.131

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

I, Dr. Karen K. Brown, worked under the direction and control of the inventor, Dr. Harold Brown, and I declare as follows:

I am familiar with the prosecution history of U.S. Serial No. 08/241,692 filed May 12, 1994, including the Office Actions mailed August 8, 1997 and April 18, 1997. I am familiar with US Patent 5,266,318 to Taylor-McCord and US Patent 5,215,759 to Mausner cited by the Examiner in said Office Action(s). I will show that the present invention was reduced to practice prior to the publication date of the Taylor-McCord and Mausner patents.

1. Filing Dates of the Taylor-McCord and Mausner Patents

The filing date of the Taylor-McCord patent is December 9, 1991. The filing date of the Mausner patent is October 1, 1991.

2. The Claimed Invention

The composition of the claims of the invention comprises two components. The first component is an active ingredient of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of polysaccharides, oligosaccharides, glycosaminoglycans, mannans, branched polysaccharides and sialylated oligosaccharides, having a molecular weight in the range of from 1,000 to less than 50,000 daltons, from 100,000 to 500,000 daltons, or greater than 750,000 daltons which is present in a pharmacologically effective amount.

The second component is an essential oil present in an amount effective to allow penetration of the dermis of mammals by the complex carbohydrate.

3. Section A from the Notebook of Dr. Karen Brown

Section A recites the use of a composition of 1% hyaluronic acid, 1% chondroitin sulfate [i.e. both ingredients within the scope of invention as active ingredients], 2% peppermint oil [essential oil], on the acne of Patient 1.

4. Section B from the Notebook of Dr. Karen Brown

Section B recites the use of a composition of 1% Dermatan sulfate with 2% wintergreen oil on the rug burns of Patient 2.

5. Section C from the Notebook of Dr. Karen Brown

Section C recites the use of a composition of 1% high molecular weight cosmetic grade hyaluronic acid plus 1% chondroitin sulfate with 2% Rosemary oil for the heat-burn of Patient 3.

6. Section D from the Notebook of Dr. Karen Brown

Section D recites the use of a composition of 98% Aloe Vera extract with 1% Tea Tree Oil on the rug burns of Patient 4.

7. Section E from the Notebook of Dr. Karen Brown

Section E shows that the formulations discussed above worked effectively.

8. Tests occurred prior to Taylor-McCord (12/9/91) and Mausner (101/91)

These tests occurred prior to December 9, 1991, which is the date that the Taylor-McCord et al. publication was filed, and prior to October 1, 1991, which is the date that Mausner was filed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or

Serial No. 08/241,692

both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

12/29/97
Date

Karen K. Brown
Dr. Karen K. Brown

Enclosures: Pages 65-73 of Laboratory Notebook

12/29/97

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AND ESSENTIAL OILS AND MEHODS OF USING THE SAME

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Honorable Commissioner of Patents
and Trademarks
Washington D.C. 20231

Sir:

I, Dr. Karen K. Brown, worked under the direction and control of the inventor, Dr.

Harold Brown, and I declare as follows:

I am familiar with U. S. Patent 4,900,550 to Lowry cited by the Examiner as teaching the composition of the immediate invention. I will show that the composition of Lowry is not effective for use in the immediate invention as the concentration of the complex carbohydrate(s) taught by Lowry are too low to be used to relieve pain, inflammation, itching and swelling.

1. Compositions described by Lowry

Lowry teaches a Softener Component containing numerous ingredients, one of which is Aloe Concentrate (8.75-10.50 weight percent).

The Cell Penetrating Component also contains numerous ingredients, one of which is Hyaluronic Acid (0.09-0.11 weight percent), another of which is hydrolyzed mucopolysaccharides (0.09-0.11 weight percent). Additionally, this composition includes Aloe Concentrate (50.00-62.00 weight percent).

The Norishment and Protectant Component of the Lowry patent contains Hyaluronic Acid (0.05-0.10 weight percent) plus hydrolyzed mucopolysaccharides (0.9-0.11 weight percent). Additionally this component contains 50% Aloe Vera Solution (57-60 weight percent).

The Examiner has cited the compositions of Lowry as teaching the immediate invention.

2. The Claimed Invention

The composition of the claims of the invention comprises two components. The first component is an active ingredient of at least one low purity or cosmetic grade complex carbohydrate selected from the group consisting of polysaccharides, oligosaccharides, glycosaminoglycans, mannans, branched polysaccharides and sialylated oligosaccharides, having a molecular weight in the range of from 1,000 to less than 50,000 daltons, from 100,000 to 500,000 daltons, or greater than 750,000 daltons which is present in a pharmacologically effective amount. The second component is an essential oil present in an amount effective to allow penetration of the dermis of mammals by the complex carbohydrate.

3. Section F from the Notebook of Dr. Karen Brown

Section F recites several preparations which contain from 0.10 to 1.0 Wt. % Hyaluronic Acid combined with 2% vol/vol Tea Tree Oil.

4. Section G from the Notebook of Dr. Karen Brown

Section G shows that there was no pain-relieving effect from the preparations containing less than 0.3 Wt. % Hyaluronic Acid combined with 2% vol/vol Tea Tree Oil. At 0.3 Wt % the Hyaluronic Acid was effective in relieving the pain and swelling of a bruise.

5. Section H from the Notebook of Dr. Karen Brown

Section H indicates that Hyaluronic acid used at a concentration below 0.3 Wt. % combined with 2% vol/vol Tea Tree Oil was not effective in relieving the pain of a shin splint.

6. Section I from the Notebook of Dr. Karen Brown

Section I indicates that Hyaluronic acid used at a concentration below 0.3 Wt. % combined with 2% vol/vol Tea Tree Oil was not effective in relieving the pain caused by chronic chondromalacia of the knees.

7. Section J from the Notebook of Dr. Karen Brown

Section J indicates that Hyaluronic acid used at a concentration below 0.3 Wt. % combined with 2% vol/vol Tea Tree Oil was not effective in relieving the pain and swelling associated with rheumatoid arthritis.

8. Section K from the Notebook of Dr. Karen Brown

Section K indicates that Hyaluronic acid used at a concentration below 0.3 Wt. % combined with 2% vol/vol Tea Tree Oil was not effective in relieving the itching associated with poison ivy.

9. Conclusion of the tests described in the Notebook of Dr. Karen Brown

When hyaluronic acid is used at a concentration below 0.3 wt. % when combined with 2% vol/vol tea tree oil, the composition will not have pain relieving effect. Thus, the lower amounts of hyaluronic acid and essential oil of the Lowry reference would be expected to be ineffective and thus not fall within the scope of the present invention. That is the Lowry compositions are not inherently pharmacologically effective.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1/31/98
Date

Karen K. Brown
Dr. Karen K. Brown

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Harold G. Brown

Serial No.

Group 1211

Filed: Divisional of Parent case
filed May 12, 1994

Examiner: H. Lee

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CARBOHYDRATES AND ESSENTIAL OILS AND METHODS OF
USING THE SAME

DECLARATION UNDER 37 CFR 1.131

Honorable Commissioner of Patents
and Trademarks
Washington D.C. 20231

Sir:

I, Dr. Harold G. Brown declare as follows:

During the time between the reduction to practice of the composition of Wintergreen Oil in combination with hyaluronic acid or chondroitin sulfate and filing of the patent application on May 12, 1994, I was preparing and testing numerous other types of complex carbohydrates and essential oils in order to expand the scope of the initial invention.

This work involved preparing formulations containing chondroitin sulfate, heparin sulfate, heparin, keratin sulfate, dermatin sulfate, glucosamine, aloe vera, dextrans, dextrose, fructose and sialic acid in combination with Eucalyptus Oil, Pine Needle Oil, White Birch Oil, Spearmint Oil, Tea Tree Oil, Peppermint Oil, Camphor Oil, Sage Oil, Johoba Oil, Cinnamon Oil, Anise Oil, Lemon Oil, Lime Oil, Orange Oil, Clove Oil, Almond Oil, White Pine Oil, Cardamon Oil, Cedar Lef Oil and Menthol. After formulation, each sample was evaluated in humans, for its effectiveness in treating various conditions. This work required several years to complete and provided the information necessary to demonstrate that a significant number of complex carbohydrates in combination with numerous essential oils are effective as described.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Filed or Issued: 12, 1994

For: A PHARMACEUTICAL COMPOSITION OF COMPLEX CARBOHYDRATES AND ESSENTIAL OILS AND METHODS OF USING THE SAME

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(c)) — SMALL BUSINESS CONCERN

I hereby declare that I am

- (☒) the owner of the small business concern identified below;
() an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN DERMAL RESEARCH LABORATORIES, INC.ADDRESS OF CONCERN 5501 NW Fox Hill Rd
PARKVILLE, MO. 64152

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A PHARMACEUTICAL COMPOSITION OF COMPLEX CARBOHYDRATES AND ESSENTIAL OILS AND METHODS OF USING THE SAME by inventor(s) described in

- (☒) the specification filed herewith
() application serial no. _____, filed _____
() patent no. _____, issued _____

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____

ADDRESS _____

() INDIVIDUAL () SMALL BUSINESS CONCERN () NONPROFIT ORGANIZATION

NAME _____

ADDRESS _____

() INDIVIDUAL () SMALL BUSINESS CONCERN () NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING KAREN K. BROWN

TITLE OF PERSON OTHER THAN OWNER _____

ADDRESS OF PERSON SIGNING 5501 NW Fox Hill RdPARKVILLE, MO. 64152SIGNATURE Karen K. Brown DATE 5/11/94